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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/169,048	10/08/1998	WILLIAM D. HUSE	P-IX-3280	5187

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EXAMINER

GARCIA, MAURIE E

ART UNIT PAPER NUMBER

1627

DATE MAILED: 03/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/169,048

Applicant(s)

Huse et al

Examiner

Maurie E. Garcia, Ph. D.

Art Unit

1627



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

THE REPLY FILED Feb 27, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires THREE months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Feb 27, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☒ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Please see attached.

4. ☐ Applicant's reply has overcome the following rejection(s):  
\_\_\_\_\_  
\_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
\_\_\_\_\_  
\_\_\_\_\_
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 10-18 and 39
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other:

### ADVISORY ACTION

#### *Attachment*

1. Applicant's After Final amendment filed February 27, 2002 raises new issues which would require further search and consideration and does not place the case in better form for appeal or in condition for allowance. Thus the amendment will not be entered.
2. Applicant's arguments are moot in view of the non-entry of the amendment. Thus, all rejections are maintained for reasons of record. The non-entry of the amendment is discussed more fully below.
3. First, the proposed amendment is deemed to require further search and consideration with respect to the added limitation of "population of five or more receptors". There was no such limitation previously in the claims directed towards a "population" of receptors. This proposed change in claim scope is deemed to raise considerable new issues, both for search and under 35 USC 112.
4. Furthermore, it appears that the proposed claims would constitute a shift in the claimed invention, which is not permitted (see MPEP 819). The claims under examination are drawn to a method of determining binding of a "collective ligand variant population" to receptors, but **not** binding of a "collective ligand variant population" to a "population of five or more receptors". The proposed claims are drawn to a method that is distinct from the method originally examined

because of the addition of a second “population” of molecules that was not present in the original claims. It is unclear exactly what is being claimed; however, depending on interpretation, the proposed claims could be construed as to read on the claims of Groups IV or V from the original Restriction Requirement (see Paper No. 10, mailed 2/28/00).

5. Moreover, again, it is unclear exactly what is being claimed; however, depending on interpretation, the proposed claims could also be deemed to contain new matter. The proposed claims are drawn to a method for determining binding of a “collective ligand variant population” to a “population of five or more receptors”. Applicant points to support in the instant specification; however, the examiner deems this to be insufficient to support the proposed amendments. There is simply not adequate support for the new concept of using a “collective ligand variant population” with another population as the proposed claims recite. In accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments made to the disclosure. Also see paragraph 6 below.

6. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date

sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support ... is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). It is completely unclear that the description as filed supports the proposed new limitations regarding the binding of a “collective ligand variant population” to a “population of five or more receptors”.

7. Lastly, in the After Final amendment Applicant also proposes to add several new claims and cancels no finally rejected claims. Moreover, the proposed new claims contain species of ligand that were not originally present that would also raise considerable new issues.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of

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a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*J Venkat*  
DR. J. VENKAT PH.D.  
SUBSTANTIVE EXAMINER  
TECHNOLOGY CENTER 1600

Maurie E. Garcia, Ph.D.  
March 14, 2002